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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,327	09/17/2003	Edmund Schiessle	SSHP0101PUSA	4212
22045	7590	06/02/2005	EXAMINER	
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			FAULCON JR, LENWOOD	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/664,327

Applicant(s)

SCHIESSLE ET AL.

Examiner

Lenwood Faulcon, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/13/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilham (U.S. Patent No. 5,622,178).

Gilham teaches of a system and method for dynamically displaying cardiac interval data using scatter-plots, that can be used for the detection of atrial fibrillation (col. 15 lines 41-44). Gilham further teaches of the system comprising an interval monitor calculates first and second cardiac intervals corresponding to a period of time between first and second heartbeats and the second interval corresponding to a period of time between the second heart beat and a third heartbeat (col. 2 lines 10-16).

Gilham also teaches of a display having first and second axes labeled with a plurality of indicators corresponding to time intervals, that displays the first and second intervals as a coordinate pair (col. 2 lines 21-27). Gilham further teaches of using successive RR intervals (col. 5 lines 65-67, col. 6 line 1).

Gilham also teaches of the system including a heartbeat analyzer that determines a clinical type for the heartbeats (col. 2 lines 33-42). Gilham further teaches of a system for evaluating scatter-plot data comprising stored data corresponding to a predefined normal pattern, in which a comparison is made between the measured

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scatter-plot data and the stored scatter-plot data (col. 4 lines 21-27). Gilham also teaches of the system being able to alert the user of the presence of clinical abnormality, for example atrial fibrillation (col. 15 lines 39-45).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilham (U.S. Patent No. 5,622,178) as applied to claim 1 and 4 above, in view of an Kamen (U.S. Patent No. 5,682,901) and further in view of Levitan et al. (U.S. Patent No. 6,731,974).

Kamen teaches of an apparatus and method for measuring autonomic activity of a patient, that comprises obtaining ECG signals, measuring the R-R interval and generating a Poincare plot from the R-R signals (col. 2 lines 11-18). Kamen further teaches of quantifying the degree of heart failure the patient may be experiencing (col. 2 lines 23-32). Kamen further teaches of identifying geometrical point patterns in the Poincare plots as an indication of the patient's health state (col. 9 lines in 24-38).

Levitan et al. teaches of a method and system for measuring heart rate variability, that comprises a obtaining and recording heartbeat-to-heartbeat intervals, during a predetermined period of time, generating a recurrence plot form the intervals

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and calculating a determinant (col. 3 lines 17-35). Levitan further teaches of classifying a patient by assigning a degree of risk for death due to heart failure (col. 3 lines 9-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Gilham as applied above with the teachings of Kamen and Levitan et al. to have a system detects atrial fibrillation by obtaining R-R intervals, generating a scatter plot based on the R-R intervals and determining a degree of heart failure based on a geometrical representation within the scatter plot. Gilham, Kamen and Levitan et al. all teach of systems that monitor a heart's activity and generate a plot according to detected signals, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art to modify the system and method as taught by Gilham by implementing electronic geometric pattern checking of the generated scatter plot to improve the detection of atrial fibrillation, since a manual observation may provide unreliable results, as suggested by Levitan et al. (col. 2 lines 52-57).

It would have also been obvious to one having ordinary skill in the art at the time of the invention to modify the system and method as taught by Gilham to have a plurality of state signals representing the state of the patient's heart, corresponding to a risk level of atrial fibrillation, since this would provide greater feedback to the patient, as taught by Levitan et al. (col. 3 lines 9-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Gilham by using a LCD visual display since the use of LCDs are commonly used because of their lightweight and ability to provide enhanced viewing.

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5. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilham (U.S. Patent No. 5,622,178) as applied to claims 1 and 4 above.

The use of analog circuits, that include preamplifiers, electronic filters and a main amplifier are commonly used in this art for obtaining measured signals. Further, digital circuits that include an A/D converter, a microcontroller, memory and stages for sampling are also commonly used in connection with analog circuits in this art. The use of batteries with audio or visual low voltage warning indicators is also commonly in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Gilham to include analog and digital circuits, as well a battery with a low voltage indicator in order to provide efficient and safe operation of the system.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. King (U.S. Patent No. 4,750,494), Throne (U.S. Patent No. 5,404,880), Morris (U.S. Patent No. 6,314,321), Kumar et al. (U.S. Patent No. 6,416,471), Ferguson et al. (U.S. Patent No. 6,454,708), Taha et al. (U.S. Patent No. 6,597,943), Ritscher et al. (US 2004/0092836), Glass et al. (WO 02/24068), Marciano et al., "Quantification of Poincare Maps for the Evaluation of Heart Rate Variability," (Computer in Cardiology, Sept. 1994, pp. 577-580), Huikuri et al., "Abnormalities in Beat-to-Beat Dynamics of Heart Rate Before the Spontaneous Onset of Life-Threatening Ventricular Tachyarrhythmias in Patients with Prior Myocardial Infarction,"

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(Circulation, American Heart Association, Vol. 93, No. 10, May 15, 1996, Seiten 1836-1844).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lenwood Faulcon, Jr.



George Manuel

Primary Examiner